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### Subpart F—Records and Reports



### Subpart G—Registration, Submission, and Notification Requirements



AUTHORITY: 21 U.S.C. 321, 342, 350a, 371.

SOURCE: 79 FR 8059, Feb. 10, 2014, unless otherwise noted.

## Subpart A—General Provisions

### § 106.1 Status and applicability of the regulations in part 106.

(a) The criteria set forth in subparts B, C, and D of this part prescribe the steps that manufacturers shall take under section 412(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(b)(2) and (b)(3)) in processing infant formula. If the processing of the formula does not comply with any regulation in subparts B, C, or D of this part, the formula will be deemed to be adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria set forth in subpart E of this part prescribe the requirements for quality factors that infant formula shall meet under section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the formula fails to comply with any regulation in subpart E of this part, it will be deemed to be adulterated under section 412(a)(2) of the Federal Food, Drug, and Cosmetic Act.

(c) The criteria set forth in subpart F of this part prescribe records requirements for quality factors under section 412(b)(1) of the Federal Food, Drug, and Cosmetic Act and for good manufacturing practices and quality control procedures, including distribution and audit records, under section 412(b)(2). If an infant formula manufacturer fails to comply with the quality factor record requirements in subpart F of this part with respect to an infant formula, the formula will be deemed to be adulterated under section 412(a)(2) of the Federal Food, Drug, and Cosmetic Act. If an infant formula manufacturer fails to comply with the good manufacturing practices or quality control procedures record requirements in subpart F of this part with respect to an infant formula, the infant formula will be deemed to be adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act. The criteria set forth in subpart F of this part also implement record retention requirements under section 412(b)(4) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart F of this part is a violation of section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)).

(d) The criteria set forth in subpart G of this part describe, in part, certain good manufacturing practices, quality control procedures, and quality factor records requirements under section 412(b)(1) and (b)(2) of the Federal Food, Drug and Cosmetic Act. If an infant formula manufacturer fails to comply with such records requirements with respect to an infant formula, the infant formula will be deemed to be adulterated under section 412(a)(2) or (a)(3) of the Federal Food, Drug, and Cosmetic Act, as applicable. The criteria set forth in subpart G of this part also describe the circumstances in which an infant formula manufacturer is required to register with, submit to, or notify the Food and Drug Administration, and the content of a registration, submission, or notification, under section 412(c), (d), and (e) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart G of this part is a violation of section 301(s) of the Federal Food, Drug, and Cosmetic Act.

### § 106.3 Definitions.

The definitions in this section and the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) shall apply to infant formula requirements in 21 CFR parts 106 and 107 of this chapter.

*Eligible infant formula* means an infant formula that could be lawfully distributed in the United States on December 8, 2014.

*Final product stage* means the point in the manufacturing process, before distribution of an infant formula, at which the infant formula is homogeneous and is not subject to further degradation due to processing.

*Indicator nutrient* means a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and uniform distribution of a premix or other substance of which the indicator nutrient is a part.

*Infant* means a person not more than 12 months of age.

*Infant formula* means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

*In-process production aggregate* means a combination of ingredients at any point in the manufacturing process before packaging.

*Major change* in an infant formula means any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer. Examples of infant formulas deemed to differ fundamentally in processing or in composition include:

(1) Any infant formula produced by a manufacturer who is entering the U.S. market;

(2) Any infant formula powder processed and distributed by a manufacturer who previously only produced liquids (or vice versa);

(3) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience;

(4) Any infant formula manufactured on a new processing line or in a new plant;

(5) Any infant formula manufactured containing a new constituent not listed in section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)), such as taurine or L-carnitine;

(6) Any infant formula processed by a manufacturer on new equipment that utilizes a new technology or principle (e.g., from terminal sterilization to aseptic processing); or

(7) An infant formula for which there has been a fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

*Manufacturer* means a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution. The term ''manufacturer'' does not include a person who prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.

*Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance.

*New infant formula* means:

(1) An infant formula manufactured by a person that has not previously manufactured an infant formula, and

(2) An infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer, or which has not previously been the subject of a submission under section 412(c) of the Federal Food, Drug, and Cosmetic Act for the U.S. market.

*Nutrient* means any vitamin, mineral, or other substance or ingredient that is required in accordance with the ''Nutrients'' table set out in section 412(i)(1) of the Federal Food, Drug, and Cosmetic Act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or that has been identified as essential for infants by the Food and Drug Administration through a FEDERAL REGISTER publication.

*Nutrient premix* means a combination of ingredients containing two or more

nutrients received from a supplier or prepared by an infant formula manufacturer.

*Production aggregate* means a quantity of product, or, in the case of an infant formula produced by continuous process, a specific identified amount produced in a unit of time, that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a master manufacturing order.

*Production unit* means a specific quantity of an infant formula produced during a single cycle of manufacture that has uniform composition, character, and quality, within specified limits.

*Production unit number or production aggregate number* means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a production aggregate or a production unit of infant formula can be determined.

*Quality factors* means those factors necessary to demonstrate the safety of the infant formula and the bioavailability of its nutrients, as prepared for market and when fed as the sole source of nutrition, to ensure the healthy growth of infants.

*Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

*Shall* is used to state mandatory requirements.

[79 FR 8059, Feb. 10, 2014, as amended at 79 FR 33070, June 10, 2014]

## Subpart B—Current Good Manufacturing Practice

### § 106.5 Current good manufacturing practice.

(a) The regulations set forth in this subpart define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under §107.100 of this chapter and is manufactured in a manner designed to prevent its adulteration. A liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container is also subject to the regulations in part 113 of this chapter, and an infant formula that is an acidified food, as defined in §114.3(b) of this chapter, is also subject to the regulations in part 114 of this chapter.

(b) The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)); the failure to comply with any regulation in part 113 of this chapter in the manufacture, processing, packing, or holding of a liquid infant formula shall render such infant formula adulterated under section 412(a)(3); and the failure to comply with any regulation in part 114 of this chapter in the manufacture, processing, packing, or holding of an infant formula that is an acidified food shall render such infant formula adulterated under section 412(a)(3).

### § 106.6 Production and in-process control system.

(a) A manufacturer shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.

(b) The production and in-process control system shall be set out in a written plan or set of procedures that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, a manufacturer shall:

(1) Establish specifications to be met;